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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/444,095	11/22/99	IBRAHIM S	ARMY-123

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EXAMINER	
SISSON, B	
ART UNIT	**PAPER NUMBER**
1655	9

DATE MAILED: 06/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/444,095	SOFI, IBRAHIM M.	
	Examiner	Art Unit	
	Bradley L. Sisson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on *23 May 2000 and 13 June 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *1-30 and 40-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 November 1999* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 31-39, in Paper No. 6, received 23 May 2000, is acknowledged. The traversal is on the ground(s) that allowance of Group II would necessitate allowance of Groups I and III. This is not found persuasive because allowance or non-allowance is not the criteria upon which restriction is based. Rather, the distinctness of the various inventions and the burden placed upon the examiner are but some of the reasons upon which a valid restriction can be based. As seen in the prior Office action, all three of the groups are drawn to different inventions having different classification and obviously requiring different searches.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of binding nucleic acids and proteins to a support in a non-specific manner (not predicated on the sequence of nucleotides or amino acids), does not reasonably provide enablement for sequence-specific binding of nucleic acids or proteins nor for conducting an amplification reaction followed by specific or non-specific binding of nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As presently worded the method of claims 31-36 has sufficient breadth of scope so to encompass specific isolation/binding of target nucleic acids or proteins to a solid support. As set forth in the preamble of claim 31, the denaturing solution does not give rise to denatured nucleic acids, be they DNA or RNA. Yet, in order for one to selectively bind a probe to target nucleic acids, there needs to be a denaturation of the target nucleic acid such that it is single stranded prior to hybridizing to the probe to the target. The specification has been found to contain suggestions that the hybridization step can be conducted subsequent to having performed polymerase chain reaction. Neither the claims nor the specification teach how one is to perform such an amplification reaction when the nucleic acid is present in a protein denaturing solution. Clearly, without something being done to the denaturation solution in which one finds the crude nucleic acid sample, the polymerase used to perform an amplification reaction would be rendered denatured and as a direct result of such, be rendered inoperative.

5. Claims 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

a. How the nucleic acid is to be prepared such that it is used in a hybridization reaction;

b. If one is to conduct an amplification reaction, just how the amplification reaction is to be performed while there is a protein denaturant present (seemingly, the protein denaturant will result in rendering the polymerase inoperative). If one is to use a peptide p[robe after amplification, and the peptide probe is an anti-histone antibody, the method needs to reflect what steps are needed so to render the amplified nucleic acid capable of being bound by the antibody, if such is even possible; and

c. Like "b", *supra*, the use of a peptide probe, e.g., an antibody, to bind the nucleic acid, while the protein denaturant is present, raises several issues. The claims need to reflect just what steps are need so to render the sample mixture susceptible to binding by another protein when the presence of the denaturant would result in the denaturation of the peptide probe.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ji et al., in view of Henco et al., Piaso et al., Lockhart et al., Tuunanen (WO 94/18564).

Ji et al., disclose a method for the isolation of nucleic acid from a lysate solution. As set forth in columns 3 and 4, the solid support can be of virtually any shape and that the capture sequence could be immobilized on a support that can be of "column packing material" as well as filter paper support. The use of magnetic beads as a suitable support is disclosed in column 4, fifth paragraph, and in the sixth paragraph, the use of wash solutions so to remove unwanted lysate materials is similarly disclosed.

Ji et al., do not teach explicitly of the use of a wand that has a surface that would bind to the nucleic acid in the lysate solution.

Henco et al., disclose the use of silica gel particles that are trapped in a network of membranes for the binding/isolation of nucleic acids from a cellular lysate solution. Column 3, penultimate paragraph, discloses the washing of contaminates out of the microparticles and the subsequent elution of the bound nucleic acid from the solid support [applicant's sample collection assembly]. The aspect of performing polymerase chain reaction is disclosed at column 3, penultimate paragraph.

Piasio et al., disclose a variety of solid support shapes that can be used in any number of binding reactions; see Figures 1-6. As seen in the Figures, the support surfaces are attached to a wand that can be inserted into a tube into which is placed a sample solution. A common feature of the support surface is the presence of a binding member and the large amount of surface area each of the support surfaces provides, thereby increasing the efficiency of the solid support to bind the target ligand. Column 3, penultimate paragraph, discloses the use of glass beads as a solid support to which the analyte of interest is bound. The use of glass speaks directly to the presence of silicon oxide.

Lockhart et al., disclose the binding of nucleic acid to a solid support. Columns 7 through 9 speak to innumerable types and shapes of solid supports as well as the associated functional groups, including silicon oxide.

Tuunanen disclose a device used in binding reactions where a solid support is attached to a wand. The wand and associated solid support is inserted into a tube that has a sample solution so to effect binding. The wand/solid support, with its associated handle, is then passed on to a series of other tubes containing additional solutions. As seen in Figures 1 and 2, elements 4 and 4.1 respectively depict various solid supports. As set forth in page 6, third paragraph, an advantage in having an increased surface area is addressed. Similarly, at page 5, first paragraph, the "body surface [applicant's sample collection assembly] has suitable protrusions and cavities 7 to increase the surface area. In this embodiment [Figure 1] they are grooves leading toward the point." Page 5, second paragraph, speaks directly to the use of multiple washing steps which are in additional tubes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Ji et al., with that of Piasio et al., Henco et al., Lockhart et al., and Tuunanen so as to arrive at a method of binding nucleic acid in a lysate solution wherein said binding is effected by a device comprising a sample collection assembly attached to a wand or shaft that is in turn attached to a cap wherein the cap/wand/sample collection assembly is inserted into a tube so as to permit the binding of nucleic acids to the sample collection assembly and is subsequently subject to a series of washing steps prior to the elution or removal of the nucleic acid from the sample collection assembly. The ordinary artisan would have been motivated to have devised a sample collection assembly that maximized surface area for as shown in the prior art of record, such was already a motivating force as an increase in surface area permitted higher ratios of contact between the sample and the solid support and the related binding of the nucleic acid to the solid support as a direct result of the nucleic acid having been brought into contact with the support. For the above reasons, and in the absence of convincing evidence to the contrary, the claimed invention has been found to have been reasonably suggested by the prior art of record and in view of the well developed nature of the subject matter to which the invention relates, the ordinary artisan would have had a reasonable expectation for success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
June 21, 2000